UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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INFOSINT, S.A.,

Plaintiff,

-against- 06 Civ. 2869 (LAK)

H. LUNDBECK A/S, et al.,

Defendants.

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MEMORANDUM OPINION

Appearances:

James Wright Galbraith
Maria Luisa Palmese
Robert V. Cerwinski
Merri C. Moken
Esther Hagege
KENYON & KENYON
Attorneys for the Plaintiff

Peter J. Armenio
Ellen A. Scordino
Jeanne M. Heffernan
Melanie R. Rupert
KIRKLAND & ELLIS LLP
Attorneys for the Defendants

LEWIS A. KAPLAN, *District Judge.*

Plaintiff charges defendants with infringing its patent for the synthesis of a chemical compound used in the manufacture of certain pharmaceuticals by selling in the United States the antidepressant drug citalopram, which defendants allegedly made in part by using plaintiff's patented

process. The matter is before the Court on defendants' motion for partial summary judgment.

Background

Plaintiff Infosint, S.A. ("Infosint") owns the patent at issue in this case, U.S. Patent No. 6,458,973 (the "'973 patent"), which claims an improved process for making the compound 5-carboxyphthalide, a compound used as an intermediate product in the synthesis of citalopram and escitalopram. Citalopram and escitalopram are well-known antidepressants marketed in the United States.[1] Plaintiff filed its application for what issued as the '973 patent with the U.S. Patent and Trademark Office ("PTO") on October 17, 2000.[2]

The compound 5-carboxyphthalide had been synthesized successfully prior to the inventors' patent application. What the inventors claimed was a superior manufacturing process, including innovations that permitted the reaction to occur in open and non-pressurized reactors, which were especially useful for large scale production in an industrial setting.[3]

In general terms, the claimed process involves adding terephthalic acid to fuming sulfuric acid containing at least 20 percent sulfur trioxide, SO_3. Fuming sulfuric acid, also known as oleum,[4] is a mixture of sulfuric acid and sulfur trioxide.[5] Next, formaldehyde or a formaldehyde

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1 *Infosint, S.A. v. H. Lundbeck A/S*, 603 F.Supp. 2d 748, 751 (S.D.N.Y. 2009).

2 Heffernan Dec. Ex. P.

3 *Id.* at col. 1:30-50.

4 *Id.* at col. 2:19.

5 *See* Pl. Ex. 3 ¶ 46; Heffernan Dec. Ex. BB; Ex. CC at 36150.

precursor[6] is added to the mixture, which is heated at 120-145º C. The resulting 5-carboxyphthalide then is isolated from the solution.[7]

Defendants, H. Lundbeck A/S and subsidiary Lundbeck, Inc. (collectively "Lundbeck"), as well as Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc. (collectively "Forest"), manufacture, market, and sell citalopram and escitalopram.[8] Lundbeck synthesizes 5-carboxyphthalide at seven facilities located outside of the United States. It manufactures citalopram and escitalopram in Denmark.[9] Forest markets and sells these pharmaceuticals in the United States under the trademarks Celexa and Lexapro, respectively.[10]

Plaintiff alleges that Lundbeck uses 5-carboxyphthalide made according to the process described in the '973 patent as an intermediate product in its production of citalopram and escitalopram. Defendants counterclaim, asserting that several claims in Infosint's '973 patent interfere with claim 1 of Lundbeck's U.S. Patent No. 6,403,813, (the "'813 patent"), which discloses its own process for synthesizing 5-carboxyphthalide.[11] That method comprises also a "reaction of

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6 Formaldehyde is a gas a room temperature. Following a *Markman* hearing, this Court construed the term formaldehyde to include "'all synthetically useful forms of formaldehyde including solid forms of formaldehyde such as paraformaldehyde and trioxane.'" *Infosint*, 603 F.Supp.2d at 756.

7 Heffernan Dec. Ex. P at col. 2:26-44; col. 2:49 - col. 4:17.

8 Ans. at 2-3.

9 *Infosint*, 603 F.Supp. 2d at 751.

10 *Id.*

11 Am. Ans. at 14.

terephthalic acid with paraformaldehyde . . . in oleum."[12]

According to defendants, Poul Dalhberg Nielsen, a Lundbeck chemist,[13] invented the process claimed in the '813 patent no later than 1986.[14] They assert that they publically disclosed this process in the United Kingdom to Her Majesty's Inspectorate of Pollution in 1994.[15] Lundbeck then filed an application for a Danish patent claiming the process on November 1, 1999.[16] On October 19, 2000, two days after Infosint filed its application for what issued as the '973 patent, Lundbeck also submitted an application to the PTO.[17] Lundbeck's U.S. application disclosed the same process that Lundbeck described in its Danish application and claimed a priority date based on that application.[18] The PTO issued defendants' '813 patent on June 11, 2002.[19] It issued Infosint's '973 patent on October 1, 2002.[20]

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12 Heffernan Dec. Ex. S at col. 4:2-18.

13 *Id.* Ex. SS at 11:11-18.

14 Am. Ans. at 15.

15 *Id.*

16 Heffernan Dec. Ex. U.

17 *Id.* Ex. S; Ex. P.

18 *Id.* Ex. S.

19 *Id.*

20 *Id.* Ex. P.

Discussion

A. Legal Standard

Summary judgment is appropriate if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law.[21] The Court must view the facts in the light most favorable to the nonmoving party,[22] and the moving party has the burden of demonstrating the absence of a genuine issue of material fact.[23] Where the burden of proof at trial would fall on the nonmoving party, however, it ordinarily is sufficient for the movant to point to a lack of evidence on an essential element of the nonmovant's claim.[24] In that event, the nonmoving party must come forward with admissible evidence[25] sufficient to raise a genuine issue of fact for trial or suffer an adverse judgment.[26]

B. Analysis

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21 *See* FED. R. CIV. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *White v. ABCO Eng'g Corp.*, 221 F.3d 293, 300 (2d Cir. 2000).

22 *See United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962); *Hetchkop v. Woodlawn at Grassmere, Inc.*, 116 F.3d 28, 33 (2d Cir. 1997).

23 *See Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970).

24 *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986); *Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 273 (2d Cir. 2001).

25 *See, e.g.*, *Nora Beverages, Inc. v. Perrier Group of Am., Inc.*, 269 F.3d 114, 123-24 (2d Cir. 2001).

26 *See, e.g.*, *Nebraska v. Wyoming*, 507 U.S. 584, 590 (1993); *Goenaga v. March of Dimes Birth Defects Found.*, 51 F.3d 14, 18 (2d Cir. 1995).

Defendants contend that Infosint's '973 patent interferes with Lundbeck's '813 patent. They allege also that they were the first to invent the interfering subject matter and that the '973 patent therefore is invalid under Section102(g)(1) of the Patent Act (the "Act").[27] They contend also that the '973 patent is invalid under Section 103 of the Act[28] because prior art exclusive of Lundbeck's own patent rendered the '973 patent's claims obvious.[29]

1. Interference-in-Fact

A patent interferes with the patent of another when the two patents "have the same or substantially the same subject matter in similar form."[30] Section 291of the Act[31] provides that "[t]he owner of an interfering patent may have relief against the owner of another by civil action, and the court may adjudge the question of the validity any of the interfering patents, in whole or in part."

A district court has jurisdiction under Section 291 only if the alleged interference is established.[32] The first step in an interference proceeding therefore is to determine whether an

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27 35 U.S.C. § 102(g)(1).

28 *Id.* § 103.

29 Am. Ans. at 14.

30 *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 934 (Fed. Cir. 2003) (citing *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1263 (Fed.Cir.2002)); *see also* 37 U.S.C. § 135(b).

31 35 U.S.C. § 291.

32 *Medichem*, 353 F.3d at 934.

interference in fact exists.[33] To do so, the federal courts, like the PTO, rely on a two-way test[34] in which:

> "[t]he claimed invention of Party A is presumed to be prior art vis-a-vis Party B and vice versa. The claimed invention of Party A must anticipate or render obvious the claimed invention of Party B and the claimed invention of Party B must anticipate or render obvious the claimed invention of Party A."[35]

This test incorporates the standards for both anticipation and obviousness under Sections 102 and 103, respectively, permitting either circumstance to satisfy one leg of the two-way test.[36] When comparing issued patents under Section 291, courts compare the disputed claims only, not the specifications or any other disclosures of each patent.[37]

Here, defendants allege that claim 1 of their '813 patent interferes with claims 1, 21, 23, and 24 of Infosint's '973 patent. Claim 1 of the '813 patent encompasses "[a] method for the preparation of 5-carboxyphthalide comprising reaction of terephtalic acid with paraformaldehyde $HO(CH_2)_nH$ in oleum."[38] The '973 patent claims in relevant part:

> "1. A process for the preparation of 5-carboxyphthalide . . . which comprises adding formaldehyde and terephtalic acid . . . to fuming

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33 *Id.*

34 *Id.*

35 *Id.* (quoting *Winter v. Fujita*, 53 U.S.P.Q.2d 1234, 1243, 1999 WL 1327616 (Bd. Pat. App. & Int. 1999)); *see also Eli Lilly & Co. v. Bd. of Regents of the Univ. of Wash.*, 334 F.3d 1264, 1267-69 (Fed. Cir. 2003) (endorsing identical interpretation).

36 *Medichem*, 353 F.3d at 934; *see also* 37 C.F.R. § 1.601(n).

37 *Slip Track Systems*, 304 F.3d at 1265.

38 Heffernan Dec. Ex. S at 745, col. 4:1-18.

sulfuric acid containing at least 20% of SO_3, heating the mixture at 120-145° C. and isolating the 5-carboxyphthalide thus obtained.

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"21. A process for the synthesis of citalopram, in which a process for the synthesis of 5-carboxyphthalide according to claim 1 is contained.

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"23. A process for the preparation of 5-carboxyphthalide . . . which comprises adding formaldehyde (or a formaldehyde precursor) and terephthalic acid . . . to fuming sulfuric acid containing at least 20% of SO_3, heating the mixture at 120-145° C. and isolating the 5-carboxyphthalide thus obtained, wherein the process is conducted in an open, non-pressurized reactor.

"24. A process for the synthesis of citalopram, comprising the process for the synthesis of 5-carboxyphthalide according to claim 23."[39]

Under the first leg of the two way test, the Court considers whether the '973 patent claims anticipate or render obvious claim 1 of the '813 patent when the '973 patent is assumed to be prior art. A claim is anticipated "if each and every limitation [is] found either expressly or inherently in a single prior art reference."[40]

Here, the '973 claims contain each limitation enumerated in claim 1 of the '813 patent. The '973 patent claims describe a process for the synthesis of 5-carboxyphthalide. As in claim 1, the '973 patent's claimed method involves the reaction of terephthalic acid with paraformaldehyde in oleum.[41] The '973 patent claims' use of the terms "formaldehyde" and "fuming

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39 *Id.* Ex. P at col. 7:2-27; col. 8:20-23; col. 8:25-56.

40 *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998).

41 Heffernan Dec. Ex. S at 745, col. 4:1-18.

sulfuric acid" rather than "paraformaldehyde" and "oleum," respectively, is of no consequence. This Court previously has construed the word "formaldehyde" as used in the '973 patent to include "'all synthetically useful forms of formaldehyde including solid forms of formaldehyde such as paraformaldehyde and trioxane.'"[42] Oleum is a synonym for "fuming sulfuric acid,"[43] which is a mixture of sulfur trioxide and sulfuric acid.[44] The '973 patent claims therefore anticipate claim 1 of the '813 patent.

Under the second prong of the two way test, the Court considers whether claim 1 of defendants' '813 patent anticipates or renders obvious any or all of the asserted '973 patent claims. As an initial matter, the broader claim 1 of the '813 patent does not contain expressly every limitation in the '973 claims. Therefore, rather than considering whether claim 1 of the '813 patent anticipates the '973 patent claims, the Court will analyze whether the prior art, presumed for this purpose to include the '813 patent, renders the '973 claims obvious.

The determination whether an invention would have been obvious under Section 103 is a legal conclusion based on factual findings as to "'(1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; and (3) the differences between the claimed invention and the prior art.'"[45] An invention is obvious under Section 103(a) if "all the elements of an invention"

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42 *Infosint*, 603 F.Supp.2d at 756.

43 *Infosint*, 603 F. Supp.2d at 758.

44 *Id.* at 751; *see also* Heffernan Dec. Ex. CC at 36150.

45 *Medichem*, 437 F.3d 1157, 1164 (Fed. Cir. 2006) (quoting *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003)); *see also Graham v. John Deere Co.*, 383 U.S. 1, 17 (1996).

are "found in a combination of prior art references."[46] In addition, a court must consider "'(1) whether the prior art would have suggested to those of ordinary skill in the art that they should . . . carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.'"[47] These are questions of fact.[48]

As discussed above, all of the elements of claim 1 of the '813 patent are found in each of the '973 claims. The '973 claims, however, contain additional limitations absent from claim 1 of the '813 patent. The question therefore becomes whether those additional limitations were obvious in light of the prior art.

The first of the additional limitations is the specification that the fuming sulfuric acid or oleum contain "at least 20% of SO_3."[49] But this element was disclosed in an article published in 1970 by LeRoy S. Forney, entitled *Reaction of Terephthalic Acid with Formaldehyde in Sulfur Trioxide Media*, ("Forney 1970").[50] According to Forney 1970, 5-carboxyphthalide is produced "cleanly and in excellent yield," when terephthalic acid and formaldehyde are reacted in "sulfur trioxide media," although "reaction media containing <20% SO_3" may result in the formation of

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46 *Medichem*, 437 F.3d at 1164.

47 *Id.* (quoting *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003)).

48 *Id.* at 1164-66.

49 Heffernan Dec. Ex. P col. 7:25-26; col. 8:49.

50 *Id.* Ex. DD.

unwanted by-products.[51] Nevertheless, the description of the reaction conducted by Forney indicated that he used 98 percent sulfuric acid, not oleum containing more than 20 percent sulfur trioxide. This reference therefore is not alone sufficient to render the '973 claims' oleum specification obvious.

However, in an article published a year later ("Forney 1971"), Forney and Anthony T. Jurewicz compared a series of reactions of formaldehyde and terephthalic acid in sulfuric acid containing varying amounts of sulfur trioxide (*i.e.*, oleum) to a series of reactions of the same two compounds in dimethyl sulfate media containing varying amounts of sulfur trioxide.[52] The authors concluded that "the conversion in both solvents reaches a maximum" at 60 percent sulfur trioxide. A graph contained in the article illustrated this finding, indicating that somewhere between 5 and 10 percent sulfur trioxide was necessary to convert the mixture to 5-carboxyphthalide and that the conversion rate increased in direct proportion to the increasing sulfur trioxide concentrations up to concentrations of 60 percent.[53]

The Federal Circuit has explained that the optimization of a value of a variable in a known process is "ordinarily within the skill of the art."[54] Here, in light of this prior art, the '973 patent's selection of a minimum of 20 percent sulfur trioxide rather than 5 or 10 percent represents an effort to improve upon what already was known. That was within the ordinary skill of the art. Furthermore, based on Forney 1971, the inventors of the '973 patent process would have had a

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51 *Id.* at 1138.

52 *Id.* Ex. NN at 1208. Later in the article, the authors refer to the former mixture as "oleum." *See id.* at 1209.

53 *Id.* at 1208.

54 *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003).

reasonable expectation that an increase in the minimum sulfur trioxide level, at least up to concentrations of 60 percent, would improve the reaction's conversion rate.

Infosint expert Dr. Goekel opines that "one of ordinary skill in the art would conclude from Forney 1971 only that liquid SO_3 is the preferred solvent for the reaction . . . . Forney 1971 therefore teaches away from . . . the use of oleum in a process for making 5-carboxyphtalide."[55] He notes that tables I and II of Forney 1971 showed "equivocal results."[56] However, table I, labeled "Effect of Added Salts on the Reaction of Formaldehyde and TPA [terephthalic acid]," bears no relation to the reaction at issue here, which did not involve the use of any salts. Table II, labeled "Solvent Effect on the Reaction of Formadehyde and TPA [terephthalic acid] at 150° for 2 Hr," demonstrates that "relatively high conversions were observed in solvents characterized by their free SO_3 content."[57] It indicated that the percentage conversion rate to 5-carboxyphthalide was 95 percent in a 30 percent sulfur trioxide and sulfuric acid solvent and 94 percent in 100 percent sulfur trioxide.[58] For a scientist seeking to synthesize 5-carboxyphthalide efficiently, a conversion rate of 95 percent – the highest yield listed in Table II – cannot be described as "teaching away" from the use of oleum. Moreover, while the percentage conversion rate between sulfur trioxide and oleum is similar, the article provides a clear alternative to the use of sulfur trioxide, which one trained in the art would know "combines with water with explosive violence" and emits "dense white fumes" when

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55 Pl. Ex. 3 ¶ 55.

56 *Id.*

57 Heffernan Dec. Ex. NN at 1208.

58 *Id.*

exposed to air.[59] Thus, rather than teaching away from the use of oleum, Forney 1971 would have indicated unequivocally to those of ordinary skill in the art that they could synthesize 5-carboxyphthalide using oleum as a solvent, and that they could expect a reasonable degree of success if they did so.

The second element present in the '973 patent claims but absent in claim 1 of the '813 patent is that the mixture be heated to 120-145 degrees Celsius. Prior art, however, disclosed similar temperatures. Forney 1971, which described the reaction in oleum, disclosed a temperature of 150 degrees Celsius.[60] An optimization of this temperature would have been within the ordinary skill in the art.[61] Moreover, similar reactions in other prior art references disclosed that temperature ranges substantially the same as that disclosed in the '973 patent had been used with success. Forney 1970 described heating the mixture to 120-130 degrees Celsius,[62] and U.S. Patent No. 3,607,884, issued in 1971 to Forney for another method of synthesizing 5-carboxyphthalide from terephthalic acid and formaldehyde ("the '884 patent"), specified that the mixture be heated to between 120-180 degrees, with a range of 120-150 degrees preferred.[63] While both of these reactions were conducted in sulfur trioxide rather than oleum, they nonetheless would have indicated to the inventors of the '973 patent that they would have a reasonable expectation of success if they used similar temperature ranges,

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59 *Id.* Ex. II at 36216.

60 *Id.* Ex. NN at 1208, 1211.

61 *See, e.g.*, *In re Peterson*, 315 F.3d at 1330.

62 *Id.* Ex. DD at 1138.

63 *Id.* Ex. EE at col. 1:28, 69-72.

especially when combined with the teaching of Forney 1971.

The third element identified by Infosint as absent from claim 1 of the '813 patent is the limitation that the 5-carboxyphthalide compound be isolated. Prior art, including the '884 patent, disclosed a method for isolating 5-carboxyphthalide following its synthesis.[64] As the claims asserted in the '973 patent do not specify the manner by which the compound is to be isolated, the prior art need not identify a particular manner for this process. Moreover, it would have been obvious to those of ordinary skill in the art that it would be necessary to isolate the end product in order for an invention of a method for synthesizing 5-carboxyphthalide to be useful commercially.

Fourth, plaintiffs point to the limitation "[a] process for the preparation of citalopram" in claims 21 and 24. While this limitation was not included in the '813 patent, the prior art disclosed that 5-carboxyphthalide was a useful intermediate compound in the synthesis of citalopram.[65] Those with ordinary skill in the art therefore would have known that 5-carboxyphthalide could be used as an intermediate in the synthesis of citalopram.

Finally, claims 23 and 24 of the '973 patent disclose that the process be "conducted

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64 *Id.* col. 2:6-11 ("[T]he product will be obtained in the form of the corresponding ester of 5-carboxyphthalide. This can be hydrolyzed by well-known methods, or saponified and acidified, to obtain the 5-carboxyphthalide. The product, however, can be poured into water to obtain the 5-carboxyphthalide directly. 5-carboxyphthalide may be purified by recyrstalization from a suitable solvent, such as acetic acid.").

65 *Id.* Ex. GG at 905, 908-09 (foreign patent issued May 14, 1998 claiming method for the preparation of citalopram and stating that the "starting materials of formula IV are commercially available or may be prepared from 5-carboxyphtalide by reaction with thionyl chloride"); *see also* 35 U.S.C. §§ 102(b) & 103(a) (prior art for purposes of obviousness analysis includes "invention patented . . . in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States").

in an open, non-pressurized reactor."[66] The '884 patent claims a similar but not identical reaction conducted at atmospheric pressure. As this Court discussed previously, a non-pressurized reaction includes, but is not limited to, a reaction conducted at atmospheric pressure.[67] It would be obvious to one with ordinary skill in the art, however, that a reaction conducted at atmospheric pressure could be conducted in a "non-pressurized" reactor.[68] Moreover, Forney 1970 noted when a reaction described therein was carried out in sealed rather than open containers.[69] The omission of such a specification in the article's description of the 5-carboxyphthalide reaction therefore indicated that the Forney 1970 reaction used an open reactor.

One matter remains for consideration, *viz.*, neither of these prior art references disclosed a reaction conducted in oleum. The only prior art reference that did disclose such a reaction, Forney 1971, used a sealed reactor.[70] In consequence, there is a question of fact as to whether the prior art would have suggested to those of ordinary skill in the art that they should carry out the reaction in an open, non-pressurized reactor and, if it had, whether those of ordinary skill would have had a reasonable expectation of success by so doing.

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66 Pl. Ex. 2 at col. 8:52-53.

67 *Infosint*, 603 F. Supp.2d at 758-59.

68 *Id.*

69 *Compare* Heffernan Dec. Ex. DD at 1138 (reaction producing terephthaloylooxyacetic acid dimethyl ester involved contents being "sealed in a glass tube") *with id.* (reaction producing 5-carboxyphthalide).

70 *Id.* Ex. NN at 1208 ("Conditions were: 1 *M* terephthalic acid and 1 *M* formaldehyde, reacted in sealed glass tubes for 1 hr at 150 ± 0.2°.").

The Court therefore concludes that there is an interference-in-fact between claims 1 and 21 of the '973 patent and claim 1 of the '813 patent. There remains, however, a genuine issue of material fact as to whether claims 23 and 24 of the '973 patent interfere with claim 1 of the '813 patent. This Court therefore has subject matter jurisdiction to determine the validity of claim 1 of the '813 patent and claims 1 and 21 but not claims 23 and 24 of the '973 patent.

2. Alleged Invalidity Under Section102(g)(1)

a. Burden of Proof

As noted, defendants' '813 patent issued on an application filed with the PTO two days after the effective filing date of the application that resulted in the '973 patent. Defendants, however, have an earlier effective filing date than plaintiff based on their earlier patent application in Denmark.[71] Infosint, with the later effective filing date, therefore is the junior party, and bears the burden of establishing priority of invention.[72]

The junior party generally bears a heightened burden of proof in patent cases because issued patents enjoy a statutory presumption of validity.[73] There is no such presumption in a Section 291 interference proceeding, however.[74] Infosint thus bears the burden of establishing priority of

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71 *Id.* Ex. S at 743 (claiming foreign application priority date of Nov. 1, 1999); 35 U.S.C. § 119.

72 *Medichem*, 437 F.3d at 1169.

73 35 U.S.C. § 282; *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031, 1036 (Fed. Cir. 2001) (quoting 35 U.S.C. § 282).

74 *Medichem*, 437 F.3d at 1169.

invention by a preponderance of the evidence rather than by the higher clear and convincing evidence standard.[75]

b. Priority of Invention

Section 102(g)(1) of the Act provides that a person is entitled to a patent unless "during the course of an interference conducted under . . . section 291, another inventor involved therein establishes . . . that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed[.]" Defendants contend that Infosint's patent is invalid under that section because defendants were the first to invent the claimed process.[76]

The first question is which party first conceived of and reduced to practice the claimed process.[77] Defendants argue that they conceived of the process and reduced it to practice in Denmark as early as 1981. They rely on the deposition testimony of '813 patent co-inventor and Lundbeck chemist, Mr. Poul Dahlberg Nielsen, a laboratory notebook and a document entitled "Developmental Chemistry Report for the bulk drug substance Citalopram Hbr."[78] Infosint disputes this, contending that the documents cited by defendants neither belong to nor name either of the two inventors listed

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75 *Id.*

76 Def. Br. at 9-10.

77 For purposes of this litigation, Infosint stipulated that it "will not contend that the subject matter claim in the ['973 patent] was conceived or reduced to practice earlier than October 1996." Heffernan Dec. Ex. A ¶ B.

78 *Id.* at 11-12; *id.* Ex. B; *id.* Ex. C.

on the '813 patent, Hans Peterson and Mr. Nielsen.[79] It argues further that Mr. Peterson cannot have had anything to do with the conception and reduction to practice of the claimed process because he did not work at Lundbeck until October 1996.[80]

Infosint's contentions do not, however, create a material issue of fact for two reasons. The first and most important is that Infosint's arguments do not take account of Mr. Nielsen's deposition testimony. Mr. Nielsen there described his employment at Lundbeck in 1977 and his responsibility for developing an industrial process for the manufacture of citalopram.[81] He explained that he had performed experiments in the laboratory beginning in 1981and that Lundbeck was performing the process on an industrial scale by 1986.[82] Infosint does not dispute the accuracy of Mr. Nielsen's testimony or even argue that Mr. Nielsen did not conceive of or reduce the process to practice. Hence, the fact that Mr. Nielsen's name is not on the documents relied on by defendants is beside the point. Furthermore, the laboratory notebook provides independent evidence corroborating Mr. Nielsen's testimony as to the date of invention, as it consists of handwritten notes dated 1981 which document the experiments about which Mr. Nielsen testified.[83]

As to Infosint's argument regarding Mr. Peterson, it cites no authority for the proposition that each inventor listed on a patent must have contributed to the subject matter of every

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79 Pl. Br. at 9-10.

80 Heffernan Dec. Ex. SS.

81 *Id.* at 11:7-13, 13:20-14:9.

82 *Id.* at 23:17-25:24.

83 *Id.* at Ex. B.

claim in a patent. Nor could it.[84] Indeed, defendants do not contend that Mr. Peterson invented claim 1 of the '813 patent.[85]

There is thus no material issue of fact that Lundbeck conceived of and reduced to practice the claimed process in Denmark by some date in 1986. Section 104(a)(1) of the Act permits an applicant for a patent in the United States, in proceedings before the PTO or the courts, to "establish a date of invention by reference to knowledge or use thereof. . . in a foreign country" if that country is a World Trade Organization member country.[86] This provision took effect on January 1, 1996, one year after the date on which the WTO Agreement entered into force with respect to the United States, and permits inventors who rely on knowledge gained in a WTO member country prior to the effective date of the statutory provision to rely on that date as their date of invention.[87] As Denmark is a WTO member country,[88] Lundbeck therefore may rely on January 1, 1996 as its date of invention.

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84 *See* 35 U.S.C. § 116 ("Inventors may apply for a patent jointly even though . . . each did not make a contribution to the subject matter of every claim of the patent.").

85 Def. Reply at 6.

86 35 U.S.C. § 104(a)(1).

87 *Id.* § 104 (effective and applicability provision of 1994 Acts) ("An applicant for a patent . . . may not establish a date of invention . . . that is earlier than 12 months after the date of entry into force of the WTO Agreement [Jan. 1., 1995] with respect to the United States by reference to knowledge or use, or other activity, in a WTO member country[.]"); Pub. L. No. 103-465 § 531(b) (1994) (note on effective date).

88 WTO, Members and Observers, Jul. 23, 2008, available at http://www.wto.org/english/theWTO_e/whatis_e/tif_e/org6_e.htm (listing Denmark as a member country with membership date of Jan. 1, 1995).

c. Suppression or Concealment

The conclusion that Infosint has not sustained its burden to demonstrate priority of invention under Section 102(g) is not the end of the analysis. Infosint nevertheless may prevail if it sustains the burden of demonstrating by a preponderance of the evidence that defendants suppressed or concealed their invention.[89] Infosint has shown that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law on this issue.

A court may infer that an invention was concealed or suppressed "based upon an unreasonable delay in filing a patent application."[90] Although Section 102(g) contains no explicit disclosure requirement, "the spirit and policy of the patent laws encourage an inventor to take steps to ensure that 'the public has gained knowledge of the invention which will ensure its preservation in the public domain.'"[91] Thus, "[a]bsent a satisfactory explanation for the delay or the presence of other mitigating facts, a prior invention will . . . be deemed suppressed or concealed within the meaning of [Section] 102(g) 'if, within a reasonable time after the completion, no steps are taken to make the invention publically known.'"[92]

As discussed above, defendants reduced the claimed invention to practice no later than the end of 1986. They filed their international patent application, from which they claim a date

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89 *Apotex*, 254 F.3d at 1036; *Young v. Dworkin*, 489 F.2d 1277, 1279 (C.C.P.A. 1974).

90 *Apotex*, 254 F.3d at 1038.

91 *Id.* (quoting *Palmer v. Dudzik*, 481 F.2d 1377, 1387 (C.C.P.A. 1973)).

92 *Id.* (quoting *Int'l Glass Co. v. United States*, 408 F.2d 395, 403 (Ct. Cl. 1969)).

of priority for the '813 patent, on November 1, 1999.[93] Defendants therefore waited about thirteen years after reducing the invention to practice to file their first patent application. Courts have held that delays of significantly less time support an inference of delay or concealment.[94] Accordingly, this delay gives rise to an inference that defendants suppressed or concealed their invention.

Defendants nevertheless argue that they did not conceal or suppress the invention because they disclosed the process to the public, prior to filing their first patent application, when they submitted an application for Integrated Pollution Control ("IPC application") to Her Majesty's Inspectorate of Pollution in the United Kingdom.[95]

Public disclosure of an invention, including disclosure outside of the United States, before the invention date of the later inventor, may demonstrate that a prior invention was not

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93 Heffernan Dec. Ex. S at 743 ('813 patent application).

94 *Shindelar v. Holdeman*, 628 F.2d 1337, 1342 (C.C.P.A. 1980) (finding suppression or concealment because no reasonable explanation was given for the two year and five month delay between reduction to practice and the filing of a patent application); *Horwath v. Lee*, 564 F.2d 948 (C.C.P.A. 1977) (sixty-six month delay supported finding of suppression or concealment); *Peeler v. Miller*, 535 F.2d 647, 655 (C.C.P.A. 1976) (four year delay in filing a patent application after the invention was perfected was unreasonably long); *Young*, 498 F.2d at 1285 (twenty-seven month delay amounted to suppression).

95 Def. Br. at 4, 13-14; Def. Reply Br. at 6-8. Defendants contend also that they disclosed their "process for making citalopram from the intermediate *5-cyanophthalide*" in its U.S. Patent No. 4,650,884, which issued in March 1987. Def. Br. at 13 (emphasis added); Heffernan Dec. Ex. H. Infosint correctly points out that this patent does not mention 5-carboxyphthalide, but rather uses 5-cyanophthalide as a starting material. Pl. Br. at 12; Heffernan Dec. Ex. H. Defendants nowhere claim otherwise, *see, e.g.*, Def. Br. at 4, and in their reply brief they omit any mention of this patent as a prior disclosure. Instead they rely exclusively on the IPC application. Def. Reply at 6-7 ("All that matters under § 102(g) is that Lundbeck chose to disclose to the public its process of synthesizing 5-carboxyphthalide . . . when it submitted its application for IPC Authorisation[.]"). The Court therefore will focus its discussion only on the IPC application.

suppressed or concealed.[96] Nevertheless, there are at least two problems with defendants' arguments.

First, any disclosures made in the application or the authorization thereof described the invention only in broad terms. The application disclosed that "[t]erephthalic acid is reacted with paraformaldehyde and oleum to form the basic carboxyphthalide molecule[.]"[97] It added further that the reaction "can be carried out in . . . glass lined reactors," and described the isolation of the compound. However, no further detail was provided. Nowhere was a reaction temperature, the ratio of the constituent ingredients, or the percentage sulfur trioxide contained in the oleum solution mentioned.[98] Indeed, the heading of this section read:

> "Stage 1 – Carboxyphthalide Production
> "Synthesis (Chemistry can be found in Appendix (CA)1)"[99]

Appendix 1 did disclose the amounts of each ingredient used and the strength of the oleum solution, but the appendix was marked "confidential."[100] The cover letter submitted with the application noted that Lundbeck claimed "commercial confidentiality" for certain information that was segregated in the two confidential appendices.[101] The authorization described the synthesis in even broader terms,

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96 *Apotex*, 254 F.2d at 1036, 1040.

97 Heffernan Dec. Ex. G at 2469.

98 *Id.*

99 *Id.*

100 *Id.* at 2558.

101 *Id.* at 2459, 2558.

summarizing defendants' manufacturing process for cyanophthalide, produced in part from 5-carboxyphthalide, in just over one page of a twenty-three page document. The relevant portion read, "Terephthalic Acid reacts with Paraformaldehyde and Oleum to form the basic Carboxyphthalide molecule to which Stages 2 to 4 will add."[102] The remaining pages provided the conditions pursuant to which Lundbeck was authorized to manufacture the particular organic chemical processes described in its application. Thus, the papers on which defendants rely did not disclose the invention here at issue.

The second, and more substantial problem, is that there is no admissible evidence that even the allegedly public portion of the IPC application or authorization ever was disclosed to the public. In support of the proposition that the information was disclosed, defendants cite a page of the application itself which stated that "[a]ll information contained within this application will be made available to the public unless there is a request to withhold any of it."[103] This statement, however, does not demonstrate that the information in the application in fact ever was disclosed.

Defendants point also to the deposition testimony of Dr. Williams, their expert witness, to demonstrate that the information was publically available.[104] Dr. Williams testified that he had called a woman at the IPC whose name he could not remember and asked her whether Lundbeck's application was publically available at the time of the call and whether "someone basically off the street in 1994 or thereabouts would have had access to the same document in hard

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102 *Id.* Ex. UU at 3493.

103 *Id.* Ex. G at 2462.

104 Def. Br. at 5.

copy."[105] Aside from the evidentiary problems with relying on the response in support of a motion for summary judgment,[106] Dr. Williams' testimony established that although the woman said she had located the document, he never saw the document that she referred to and thus could not say how many pages it contained, whether anything was redacted from it, and whether it included the confidential appendices or cover letter. Indeed, he could not in fact testify as to the contents of the document at all because he had not requested that the woman send or fax him the document.[107]

Additionally, defendants point to screen shots of a Google search conducted on an unknown date to demonstrate that Lundbeck's IPC application or authorization was publically available. The Google search apparently led to the website of the British government's Environment Agency. A search of that agency's website resulted in a page containing the name "Lundbeck Pharmaceuticals LTD" and a license number that matches that of defendants' IPC authorization. However, the printout states, "N.B. The level of detail will not be the same for all results. If you require further information for a specific licence . . . fill in the required contact details and [an email] will be sent to our office for processing."[108] The remaining printouts provide no indication that any

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105 Heffernan Dec. Am. Ex. JJ at 41:12-18.

106 Only admissible evidence may be considered in passing on motions for summary judgment. *See Nora Beverages, Inc. v. Perrier Group of Am., Inc.*, 269 F.3d 114, 123-24 (2d Cir.2001); *Nora Beverages, Inc. v. Perrier Group of Am., Inc.*, 164 F.3d 736, 746 (2d Cir.1998); *Raskin v. Wyatt Co.*, 125 F.3d 55, 65-66 (2d Cir.1997).

Dr. Williams' testimony regarding the statements of the unnamed woman at the IPC, which is offered for the truth of the matters asserted, is inadmissible hearsay.

107 Heffernan Dec. Am. Ex. JJ at 41:12-55:16.

108 Heffernan Dec. Ex. AA at 37953.

further information could be obtained from Google or the Environmental Agency's website regarding Lundbeck's IPC application or authorization. Nor is there any evidence regarding what, if anything, one would have received in response to a request for further information. Finally, the printouts provide no indication as to what a member of the public could have obtained via an online search as of 1994, when Lundbeck filed its IPC application, or any other date prior to October 17, 2000, the date the '973 patent application was filed.[109] In consequence, there is no admissible evidence that the IPC application or authorization were available to the public prior to the start of this litigation.

Even if there were, the IPC application and authorization would be insufficient to overcome the inference that defendants suppressed or concealed the invention. In *Apotex*, the case relied on by the defendants, the Federal Circuit concluded that several disclosures in a foreign country were sufficient to rebut the inference that a pharmaceutical manufacturer had suppressed or concealed its process patent for the manufacture of a drug. There, however, the manufacturer had "widely distributed" in Canada a product monograph that disclosed the ingredients it used in its manufacturing process.[110] The ingredients were disclosed also in DICTIONNAIRE VIDAL, a French

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109 Larry Page and Sergey Brin, the founders of Google, did not obtain funding or incorporate Google, Inc. until 1998. In 1993, there were fewer than 100 websites in existence. Page and Brin did not begin working on the project now known as Google until sometime in 1994. David Hart, *On the Origins of Google*, NATIONAL SCIENCE FOUNDATION, http://www.nsf.gov/discoveries/disc_summ.jsp?cntn_id=100660&org=NSF (Aug. 17, 2004), last visited May 21, 2009. It therefore is extremely improbable that a member of the public could have obtained any relevant information at all from the IPC by conducting a Google search in 1994.

110 *Apotex*, 254 F.3d at 1040.

pharmaceutical dictionary.[111] Moreover, the manufacturer provided "a step-by-step description of the process" in testimony during a trial in Canada.[112]

Here, even if the Court assumed that the IPC application and authorization would have been available to a member of the public upon request, they would not have been widely distributed or published in a trade reference. Nor were detailed, "step-by-step" instructions ever disclosed, even in the IPC documents. Such a partial disclosure would not provide the public with the benefit of the invention,[113] and thus would fail to serve the public policy of "encourag[ing] an inventor to take steps to ensure that 'the public has gained knowledge of the invention' . . or else run the risk of being dominated by the patent of another."[114] The Court therefore concludes that defendants suppressed or concealed the invention. Accordingly, claim 1 of the '813 patent is invalid.

3. Alleged Invalidity Under Section 103

The Court has considered already whether prior art rendered the '973 patent claims obvious under Section 103.[115] This determination, however, was made under the second prong of the two-way test, the part of that test under which the '813 patent was presumed to be prior art.[116]

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111 *Id.* at 1034, 1040.

112 *Id.* at 1040.

113 *See id.*

114 *Id.* at 1038.

115 *See* Part B.1, *supra*.

116 *See Medichem*, 353 F.3d at 934.

Given the Court's conclusion that claim 1 of the '813 patent is invalid because the invention it described was suppressed or concealed, the Court now must determine whether the prior art exclusive of the '813 patent would have rendered claims 1 and 21 of the '973 patent obvious. Nonetheless, much of the Court's earlier obviousness analysis still applies here.

The remaining elements of claims 1 and 21 that must be analyzed under Section 103 are (1) a process for the preparation of 5-carboxyphthalide, (2) "which comprises adding formaldehyde (or a formaldehyde precursor) and terephthalic acid[,]" (3) to fuming sulfuric acid.[117] First, assuming without deciding that "a process for the preparation of 5-carboxyphthalide" is a claim limitation rather than non-limiting preamble,[118] prior art, including the '884 patent and both Forney articles disclosed methods for the synthesis of 5-carboxyphthalide. Second, Forney 1971 disclosed (1) the addition of formaldehyde and terephthalic acid (2) to fuming sulfuric acid or oleum.[119] Forney 1971 therefore disclosed the elements of claims 1 and 21 not analyzed above. Furthermore, because the reaction described in Forney 1971 resulted in the successful synthesis of 5-carboxyphthalide, the Court concludes that the article would have suggested to those of ordinary skill in the art that they would have had a reasonable expectation of success if they reacted formaldehyde and terephthalic acid in oleum. Accordingly, the Court holds that claims 1 and 21 of the '973 patent were rendered obvious by prior art.

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117 Heffernan Dec. Ex. P at col. 7:2-27; col. 8:20-23.

118 *Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1295 (Fed. Cir.2004).

119 *See* Heffernan Dec. Ex. NN.

Conclusion

For the foregoing reasons, defendants' motion for partial summary judgment [docket item 75] is granted to the extent that the Court concludes that claims 1 and 21 of the '973 patent are invalid, and dismisses so much of the amended complaint as alleges infringement of claim 1 of the '973 patent and all claims dependent thereon. It is denied in all other respects. As the Court has concluded also that claim 1 of the '813 patent is invalid, Count II of defendants' counterclaim is dismissed. The Court will hold a status conference on June 17 at 4:00pm.

SO ORDERED.

Dated: May 28, 2009

Lewis A. Kaplan
United States District Judge

(The manuscript signature above is not an image of the signature on the original document in the Court file.)